K001762

JUN 1 3 2000

5.0 510(k) Summary.

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §.807.92.

1. The submitter of this premarket notification is:

Ulf Borg
PULSION Medical Systems, Inc.
P.O. Box 2637
20462 Chartwell Center Drive, Suite A
Cornelius, NC 28031
Tel.: 704.655.8844
Fax.: 704.655.8866

This summary was prepared on June 8, 2000.

2. The name of this device is the PULSION Continuous Pulse Contour Cardiac Output System with accessories. The common name is the PiCCO System. Classification names are as follows:

REGULATION NUMBER	CLASSIFICATION NAME
870.1435	Single-function, preprogrammed diagnostic computer

3. The PiCCO Cardiac Output Device is substantially equivalent to the Baxter Cardiac Output Computer COM-3 marketed pursuant to K896930 and American Edwards Laboratories Critical care Explorer marketed pursuant to K842105.

4. The PiCCO Cardiac Output System is a microprocessor based device that, when coupled with the Pulsion Medical Accessories (K991886, Trade name: Pulsiocath Catheter Set with Pulsion J-guidewire, and the PCCO Monitoring kit with Pulsion Injectate In-Line Sensor), will measure and display cardiac output parameters. A coded error message is triggered and displayed in the event of malfunction.

5. The device has the same intended use as the legally marketed predicate devices.

6. The technological characteristics are the same or similar to those found with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ulf Borg
Director of Clinical Affairs
Pulsion Medical Systems
P.O. Box 2637
20462-A Chartwell Center Drive
Cornelius, NC 28031

JUN 1 3 2000

Re: K001762
Pulsion Continuous Pulse Contour Cardiac Output (PiCCO) system
Regulatory Class: II (two)
Product Code: KFQ
Dated: June 8, 2000
Received: June 9, 2000

Dear Mr. Borg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K001762

Device Name: PULSION Continuous Pulse Contour Cardiac Output System

Indications For Use:

The PULSION PiCCO is intended for determination and monitoring of cardiopulmonary and circulatory variables. Cardiac output is determined both continuously through pulse contour analysis and intermittently through thermodilution technique. In addition, the PiCCO measures heart rate, systolic, and diastolic, and derives mean arterial pressure. Analysis of the thermodilution curve in terms of mean transit time and downslope time is used for determination of intravascular fluid volumes. If a patient's weight and height are entered, the PiCCO presents the derived parameters indexed to body surface area.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000 1762